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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,560	12/05/2003	Aleandro DiGianfilippo	BBM-103US	9986
23122	7590	06/29/2006	EXAMINER	
RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980			CABRERA, ZOILA E	
			ART UNIT	PAPER NUMBER
			2125	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,560	<b>Applicant(s)</b> DIGIANFILIPPO ET AL.	
	<b>Examiner</b> Zoila E. Cabrera	<b>Art Unit</b> 2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                                       |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/28/04:01/17/06</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 12-15, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kircher et al. (US 6,975,924) in view of de la Huerga (US 7,006,894).

Kircher discloses:

1. A compounding control method to prepare a compounded mixture for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle, the method comprising the steps of: a) determining whether said plurality of source solutions conform to a predetermined configuration (Fig. 4A, i.e. concentration within allowed range?; Col. 12, lines 37-Col. 13, line 5); b) **at least one of** providing an alert to an operator and preventing compounding based on said determining step a) (Fig. 4A Display Alarm; Col. 14, line 57 to Col. 15, line 20; Col. 19, lines 1-4); e) accepting mixture inputs for one or more of said plurality of source solutions (Fig. 4A Input Prescription; Col. 8, lines 18-28); and f) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture (Col. 11, lines 1-13).

2. The method according to claim 1, further comprising the steps of: determining a nutritional assessment of a patient; comparing said mixture inputs with said nutritional assessment; and providing an output to a user based on said comparison (Col. 7, line 54 to Col.8, line 39).

3. The method according to claim 1, further comprising the steps of: determining if a lipid source solution and a dextrose source solution one of immediately follow or immediately precede one another; generating an alert to a user based on said determination; and preventing further processing of the compounded mixture until at least one buffer source solution is selected to be provided between said lipid source solution and said dextrose source solution (Col. 10, lines 53-57; Col. 9, lines 38-40; Col. 9, lines lines 65 to Col. 10 line 5).

12. The method according to claim 1, further comprising the steps of: determining if selection of said source solutions may form an insoluble precipitate; and generating an alert signal based on said comparison (Col. 10, lines 1-5).

14. The method according to claim 1, wherein said mixture inputs are received via a touch screen display (Fig. 1).

15. The method according to claim 14, further comprising the step of selectively

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deactivating a tactile input of said touch screen display for a predetermined period to allow for cleaning of a surface of said touch screen display (Fig. 1, i.e., turn off computer).

18. The method according to claim 1, further comprising the steps of: determining if a plurality of said compounded mixture are to be prepared; determining if any of a plurality of additive solutions are to be part of said compounded mixture; determining if any of said plurality of additive solutions may be pooled into a pooled additive solution; urging at least one of said plurality of additive solutions into a pooled additive solution container; and designating said pooled additive solution as a further source solution for preparation of said compounded mixture (Col. 6, lines 24-35).

19. The method according to claim 1, wherein the urging step further comprising the steps of: determining if a container of any of said source solutions dictate a low flow rate; and setting said urging for said source solution to have a reduced upper speed limit based on said determining step in order to prevent a false flow rate alarm condition (Col. 6, lines 36-43).

However Kircher does not disclose some limitations of claims 1, 20, 21 and the limitations of claims 4, 7, and 13. But de la Huerga discloses such limitations as follows:

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As for claim 1,

c) determining respective expiration dates of said plurality of source solutions (Col. 15, lines 4-16); d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c) (Col. 15, lines 18-21).

As for claims 4, 7 and 13,

4. The method according to claim 1, further comprising the step of generating a bar coded label based at least in part on a composition of the compounded mixture in the mixture receptacle (Fig. 5, Col. 7, lines 9-11).

7. The method according to claim 1, wherein said determining step c) is based at least in part on a bar code scan of said source solution (Col. 13, lines 57-62; Col. 15, lines 4-21).

13. The method according to claim 1, further comprising the step of: generating a label comprising indicia indicative of attributes of said compounded mixture (Fig. 5).

As for claims 20-21, the same citations applied to claims 1 and 18 above apply as well for these claims.

Therefore, it would have been obvious to a person of the ordinary skill in the art at the time the invention was made to combine the teachings of Kircher with the teachings of de la Huerga because it would provide an improved system wherein information about expired solutions or medication that exceeds shelf life can be easily identified and thereby an alarm or display may be activated when such an occurrence arises (Col. 6, lines 13-33).

2. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kircher et al. (US 6,975,924) and de la Huerga (US 7,006,894) and further in view of Christ et al. (US 2003/0036812 A1).

Kircher and de la Huerga disclose the limitations of claim 1 above but fail to disclose the limitations of claims 8-10. However, Christ teaches such limitations as follows:

8. The method according to claim 1, wherein said urging step f) is based at least in part on a proportional-integral-derivative (PID) control of a pump element of said compounding device ([0002]; [0007]).

9. The method according to claim 1, further comprising the steps of: receiving an input signal indicative of pump motor speed error; and sending an output correction signal to said pump element to compensate for said motor speed error ([0017]).

10. The method according to claim 9, further comprising the steps of: determining a

direction of rotation of at least a portion of said pump element; comparing said direction to a desired direction of rotation; and setting an alarm condition based on said comparison ([0016]; [0021]).

Therefore, it would have been obvious to a person of the ordinary skill in the art at the time the invention was made to combine the teachings of Kircher and de la Huerga with the system of Christ because it would provide an improved system for automatically retuning closed-loop servo motors and thereby compensate for any errors (Christ, Abstract; [0016]-[0017]; [0021]).

### ***Allowable Subject Matter***

3. Claims 5-6, 11, and 16-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

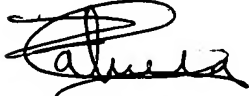
4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning communication or earlier communication from the examiner should be directed to Zoila Cabrera, whose telephone number is (571) 272-3738. The examiner can normally be reached on M-F from 8:00 a.m. to 5:30 p.m. EST (every other Friday).



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If attempts to reach the examiner by phone fail, the examiner's supervisor, Leo Picard, can be reached on (571) 272-3749. Additionally, the fax phones for Art Unit 2125 are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist at (703) 305-9600.

A handwritten signature in black ink, appearing to read 'Zoila Cabrera', with a stylized flourish at the end.

Zoila Cabrera  
Primary Examiner  
6/26/06